IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	Confirmation No.: 8295
Gary K. Michelson)	
Serial No.: 09/921,844	ý	Group Art Unit: 3738
Filed: August 3, 2001)	Examiner: Bruce E. Snow
For: SPINAL IMPLANT SURFACE)	
CONFIGURATION)	

Mail Stop RCE Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

DECLARATION UNDER 37 C.F.R. § 1.131

- I, Gary K. Michelson, declare as follows:
- I am the named inventor of the above-identified application and am the sole inventor of the subject mater described and claimed therein.
- The present application was filed on August 3, 2001 and claims priority under 35 U.S.C. § 120 to U.S. Application No. 09/457,228 (the "228 Application"), filed on December 8, 1999.
- 3. Prior to November 24, 1999 (the earliest effective filing date listed on the face page of U.S. Patent No. 6,592,624 to Fraser), I reduced to practice in this country the invention as described and claimed in the above-identified application. Attached as Exhibits A, B and C are photographs of an interbody spinal implant having a surface configuration with a rearward facet which is "back cut." The implant shown in Exhibits A and B was machined on my directions and in my possession prior to November 24, 1999.
- 4. Attached as Exhibit D is a drawing sheet of Figs. 12-15 as filed in the '228 application. Figs. 12-15 show an expanded view of the type of surface configuration machined on the surface of the implant shown in Exhibits A to C. Aside from the number of surface projections shown in Fig. 12, the surface configuration shown in

Figs. 12-15 is a faithful depiction of the surface configuration machined on the surface of the implant shown in Exhibits A to C.

The relationship of the subject matter of independent claims 1 and 219 to the surface configuration shown in Exhibits A to D is set forth below.

(a) Independent claim 1

Preamble: an Interbody spinal implant for insertion between adjacent vertebral bodies of a human spine is shown in Exhibits A to C.

Paragraph 1: the implant includes a leading end for introduction into the spine, an opposite trailing end, and spaced apart sides therebetween (see Exhibits A to C). The implant inherently has a mid-longitudinal axis passing through the leading and trailing ends.

Paragraph 2: the implant has opposite upper and lower surfaces between the leading and trailing ends and spaced apart sides, the upper surface being adapted for placement in engagement with the bone of one of the vertebral bodies and the opposite lower surface being adapted for placement in engagement with the bone of the other of the vertebral bodies when the implant is placed between the adjacent vertebral bodies (see Exhibits A to C).

Paragraph 3: a plurality of surface projections are formed on the upper and lower surfaces of the implant (see Exhibits A to C; note that the top surface of the implant is generally a mirror image of the bottom surface of the implant). At least a first and second of the projections each have at least one forward facet directed at least in part toward the leading end (see Exhibits A and B), at least one rearward facet directed at least in part toward the trailing end (see Exhibits C and D), and opposed side facets directed generally toward the sides of the implant (see Exhibits A to D). Each side facet has a perimeter and a base (see Exhibits A and D). Each forward facet and rearward facet has a length and a slope. The length of the forward facet is longer than the length of the rearward facet (see Exhibits B, C and D). Each of the forward facet has a perimeter with a base, the base of the perimeter of each side facet being longer than the base

of the perimeter of the forward facet (see Exhibits B and D). The slope of the reward facet is steeper than the slope of the forward facet (see Exhibits C and D). At least a portion of the rearward facet of the first surface projection overlies a portion of the forward facet of the second surface projection (see Exhibit D).

(b) Independent claim 219

Preamble: an interbody spinal implant for insertion between adjacent vertebral bodies of a human spine is shown in Exhibits A to C.

Paragraph 1: the implant includes a leading end for introduction into the spine, an opposite trailing end, and spaced apart sides therebetween (see Exhibits A to C). The implant inherently has a mid-longitudinal axis passing through the leading and trailing ends.

Paragraph 2: the implant has opposite upper and lower surfaces between the leading and trailing ends and spaced apart sides, the upper surface being adapted for placement in engagement with the bone of one of the vertebral bodies and the opposite lower surface being adapted for placement in engagement with the bone of the other of the vertebral bodies when the implant is placed between the adjacent vertebral bodies (see Exhibits A to C).

Paragraph 3: a plurality of surface projections are formed on the upper and lower surfaces of the implant (see Exhibits A to C; note that the top surface of the implant is generally a mirror image of the bottom surface of the implant). Each of the surface projections has a base with a maximum width and a maximum length greater than the maximum width, the maximum width of the base being transverse to the maximum length of the base (see Exhibits B and D). At least a first and a second of the surface projections each have a peak (see Exhibits A to D). The implant includes at least one forward facing facet directed at least in part toward the leading end, at least one rearward facet directed generally toward the sides of the implant (see Exhibits A to C). The side facets are located between the forward facet and the rearward facet (see Exhibits A, C

and D). Each of the forward facet and rearward facet has a length and a slope, the length of the forward facet being longer than the length of the rearward facet (see Exhibits B, C and D). The forward facet has a maximum length as measured along a line parallel to the maximum length of the base, the maximum length of the forward facet being greater than the maximum length of the base (see Exhibit D). At least one forward facet and at least one rearward facet converges at the peak (see Exhibits A to D). The rearward facet has a perimeter with a first side and a second side, the first and second sides of the perimeter being in a convergent relationship and having a first included angle therebetween proximate the peak (see Exhibits C and D). The forward facet has a perimeter with a first side and a second side, the first and second sides of the perimeter being in a convergent relationship and having a second include angle therebetween proximate the peak (see Exhibits A to D). The first included angle is greater than the second included angle (see Exhibit D).

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that the statements were made with the knowledge that wiliful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patents issuing thereon.

Dated: See 30, 2010 By: No. Michelson

Exhibit 4

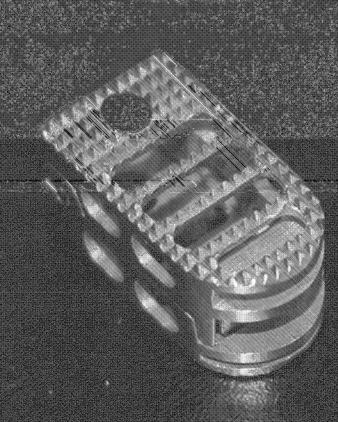


Exhibit B

